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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 11/05/2003

JOSEPH LUCCI, ESQ.
WOODCOCK WASHBURN LLP
ONE LIBERTY PLACE
46TH FLOOR
PHILADELPHIA, PA 19103

EXAMINER	
FAY, ZOHREH A	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/05/2003

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/802,709	03/08/2001	Andrew C. Lam	ARC2865N1	1161

TITLE OF INVENTION: METHODS AND DEVICES FOR PROVIDING PROLONGED DRUG THERAPY

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1330	$300	$1630	02/05/2004

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 10/03) Approved for use through 04/30/2004.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (703) 746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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09/802,709	03/08/2001	Andrew C. Lam	ARC2865N1	1161

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nonprovisional	NO	$1330	$300	$1630	02/05/2004

EXAMINER	ART UNIT	CLASS-SUBCLASS
FAY, ZOHREH A	1614	514-532000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent); ❑ individual ❑ corporation or other private group entity ❑ government

4a. The following fee(s) are enclosed:

❑ Issue Fee
❑ Publication Fee
❑ Advance Order - # of Copies _____

4b. Payment of Fee(s):

❑ A check in the amount of the fee(s) is enclosed.
❑ Payment by credit card. Form PTO-2038 is attached.
❑ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

Director for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature) (Date)

NOTE; The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

TRANSMIT THIS FORM WITH FEE(S)

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FAY, ZOHREH A	
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DATE MAILED: 11/05/2003

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

PTOL-85 (Rev. 10/03) Approved for use through 04/30/2004.

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FAY, ZOHREH A	
ART UNIT	**PAPER NUMBER**
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DATE MAILED: 11/05/2003

Notice of Fee Increase on October 1, 2003

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after October 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on October 1, 2003. See Revision of Patent Fees for Fiscal Year 2004; Final Rule, 68 Fed. Reg. 41532, 41533, 41534 (July 14, 2003).

The current fee schedule is accessible from (http://www.uspto.gov/main/howtofees.htm).

If the fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due" but not the correct amount in view of the fee increase, a "Notice of Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice of Pay Balance of Issue Fee," if the response to the Notice of Allowance is to be filed on or after October 1, 2003 (or mailed with a certificate of mailing on or after October 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously-paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Effective October 1, 2003, 37 CFR 1.18 is amended by revising paragraphs (a) through (c) to read as set forth below.

Section 1.18 Patent post allowance (including issue) fees.

(a) Issue fee for issuing each original or reissue patent, except a design or plant patent:
- By a small entity (Sec. 1.27(a)) $665.00
- By other than a small entity $1,330.00

(b) Issue fee for issuing a design patent:
- By a small entity (Sec. 1.27(a)) $240.00
- By other than a small entity $480.00

(c) Issue fee for issuing a plant patent:
- By a small entity (Sec. 1.27(a)) $320.00
- By other than a small entity $640.00

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

Notice of Allowability	Application No.	Applicant(s)	
	09/802,709	LAM ET AL.	
	Examiner	Art Unit	
	Zohreh Fay	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendments and remarks filed on Octoer 15, 2003*.
2. ☒ The allowed claim(s) is/are *37 and 46-50*.
3. ☒ The drawings filed on *08 March 2001* are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

8. ☐ CORRECTED DRAWINGS must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No. ____.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1☐ Notice of References Cited (PTO-892)
2☐ Notice of Informal Patent Application (PTO-152)
3☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
4☐ Interview Summary (PTO-413), Paper No.____ .
5☐ Information Disclosure Statements (PTO-1449), Paper No. ____.
6☐ Examiner's Amendment/Comment
7☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
8☐ Examiner's Statement of Reasons for Allowance
9☐ Other

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200

ALLOWED REVIEW

Application Number	Notice Of Allowance	Examiner
09/802,709	05-Nov-03	FAY, ZOHREH A

SECTION XI. File Wrapper

Reasons for Allowance (R/A)

Did the Examiner write a Reasons for Allowance (R/A)? ○ Yes ◉ No ○ N/A

If yes,

Is the R/A clear and complete? ○ Yes ○ No

If no,

Does the record as a whole indicate a R/A was necessary? ○ Yes ◉ No

Comments:

Interviews

Was there an interview regarding the merits of the case relevant to the action reviewed? ○ Yes ◉ No

If yes,

Was Summary Form PTOL-413 completed? ○ Yes ○ No

Is the record of the interview clear and complete? ○ Yes ○ No

Comments:

Claims

Were claims treated in an inappropriate manner on non-substantive issues? ○ Yes ◉ No

If yes,

☐ claims are present that were not addressed.

☐ claims previously withdrawn from consideration should have been cancelled.

☐ improper dependent claims were not properly treated.

☐ other

Comments:

Sequence Rules

Does the application contain nucleotide and/or amino acid sequences? ○ Yes ◉ No

If yes,

Did the examiner properly handle Sequence Compliance Issues? ○ Yes ○ No

Comments:

ALLOWED REVIEW

Application Number	Notice Of Allowance	Examiner
09/802,709	05-Nov-03	FAY, ZOHREH A

Section XIV. Indicia of Commendable/Outstanding

Patentability Determination: Indicia of Commendable/Outstanding

The record developed by the examiner shows an indication of allowable subject matter at the earliest time which is consistent with the file record and prosecution of the application. ☐Yes

Through the rejections and arguments made by the examiner, an appropriate line of patentability is established which results in amendment(s) properly limiting the scope of an ☐Yes

The search record in the application clearly shows that the examiner construes the claimed subject matter in its broadest reasonable interpretation and seeks to develop prior art from the appropriate peripherally related art areas. ☐Yes

Action Taking: Indicia of Commendable/Outstanding

The statements of rejection, objection, and response to arguments clearly and concisely present the positions taken or recommended in the resulting Office actions including a thorough substantive explanation to convey those positions to the applicant. ☐Yes

The Office action usually refer an applicant's attention to relevant and helpful elements, figures, and/or text upon which the Office action relies to support the position taken. ☐Yes

The Office action indicates that the principle of compact prosecution is being fully followed. Note, the principle of compact prosecution comprises conducting an initial search which is as complete as possible including consultation with an expert in the art where the examiner lacks such expertise (see search guidelines); placing art of record which meets both the concept and the wording of the claims as well as other art which is pertinent to significant though unclaimed features of the disclosed invention; and issuing a first Office action which clearly explains the examiner's position on each essential issue in such detail that absent some unexpected consideration the next Office action may be made final. ☐Yes

Patent Examining Function: Indicia of Commendable/Outstanding

Check one of the following statement if applicable:

☐ The Office action is formulated to advance the prosecution, correct other informalities, and develop a complete file wrapper record. The Office action also is such that it leaves little room for improvement. The Office action clearly and concisely presents the positions taken.

☐ The entire Office action is complete and accurate and does not require any substantial revision. The Office action effectively conveys the positions taken.

Comments:

PLEASE DELIVER TO:

GWEN PAYNE

CM1-7D11

ALLOWED REVIEW

POTENTIAL CLEAR ERROR

REVIEWER - ATTACH TO APPLICATION

ALLOWED REVIEW

Application Number	Art Unit	Notice of Allowance	Examiner
09/802,709	1614	05-Nov-03	FAY, ZOHREH A

Omitted Rejections

Is there a potential clear error for omitting a rejection? (The rejection you propose must be reasonable) ◉ Yes ○ No

If yes, check all that apply

- ☑ 35 U.S.C. 102
- ☐ 35 U.S.C. 103
- ☑ 35 U.S.C. 112, first paragraph, written description
- ☐ 35 U.S.C. 112, first paragraph, enablement
- ☐ 35 U.S.C. 112, second paragraph
- ☐ 35 U.S.C. 101 (utility)
- ☐ 35 U.S.C. 101 (non-statutory subject matter)
- ☐ Double Patenting (statutory, ODP)
- ☐ Other (e.g., Best Mode)

ALLOWED REVIEW

Application Number	Notice Of Allowance	Examiner
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Search

Initial Data Capture Points

Was art provided from an ESS before first action?	○ Yes	○ No	
Was any IDS improperly treated?	○ Yes	◉ No	○ N/A
Was a text search performed by the Examiner?	◉ Yes	○ No	
Was it non-patent literature?	◉ Yes	○ No	
Is the search strategy printout present?	◉ Yes	○ No	○ N/A
Was the inventorship searched by the Examiner?	◉ Yes	○ No	
If any TC or specialized art has identified specific search requirements in addition to or in exclusion of the above requirements, were these specific requirements complied with?	○ Yes	○ No	◉ N/A
Were foreign patent documents cited by the Examiner on an 892?	○ Yes	◉ No	
Were NPL documents cited by the Examiner on an 892?	○ Yes	◉ No	
Did the Examiner perform a new search in a 2nd/subsequent action?	◉ Yes	○ No	○ N/A
Did the Examiner update all searches in a subsequent action?	◉ Yes	○ No	○ N/A
Did an ESS submit a new search report in a 2nd/subsequent action?	○ Yes	○ No	○ N/A
Was there new art found by the Examiner that was applied in a 2nd/subsequent action?	◉ Yes	○ No	○ N/A
Has a search been performed by the Reviewer?	○ Yes	◉ No	

Overall Rating of the Search

◉ Adequate

○ Less than Adequate

Comments:

ALLOWED REVIEW

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Section III. 35 U.S.C. 102

Correctness of 35 U.S.C 102 Rejections

Were all 35 U.S.C 102 rejections reasonable? ○ Yes ○ No

(No indicates potential clear error)

If no, indicate the problem (check all that apply)

- ☐ Claimed features not found in the reference.
- ☐ Wrong subsection of 35 U.S.C. 102 used.
- ☐ Date of the reference no good.
- ☐ Inherency applied improperly.
- ☐ Improper official notice.
- ☐ Other

Comments:

Clarity of 35 U.S.C 102 Rejections

Were all 35 U.S.C. 102 rejections formulated in a clear manner? ○ Yes ○ No

(No indicates potential clear error)

Were claim limitations matched to the art? ○ Yes ○ Sometimes ○ No

Was any statement of inherency clearly explained? ○ Yes ○ Sometimes ○ No ○ N/A

Comments:

35 U.S.C 102 Rejection(s) That Should Have Been Made

Give a brief description of the proposed35 U.S.C. 102 rejections(s) that should have been made:

Claims 37 and 46-48 are rejected under 35 USC 102(b) as anticipated over J. W. Hubbard et al (J. of Pharmaceutical Sciences, Vol 78, No. 11, November 1989, 944-947.

The claims are drawn to a method for treating Attention-Deficit Disorder (ADD) or Attention-Deficit Hyperactivity Disorder (ADHD) in a patient comprising administering a pharmaceutically acceptable composition comprising 100 ng to 500 mg of methylphenidate (MPH) to achieve a substantially ascending methylphenidate plasma drug concentration over a time period of about 5.5 hours (claim 37). The specification (page 16, lines 1-8) defines "ascending release rate" as "a periodic release rate that is increased over the immediately-preceding periodic release rate, where the periodic intervals are the same. For example, when the quantity of drug released from a dosage form is measured at hourly intervals and the quantity of drug released during the fifth hour following administration (determined at t=5hours) is greater than the quantity of drug released from the dosage form during the fourth hour following administration (determined at t=4 hours), an ascending release rate from the fourth hour to the fifth hour has occurred."

Hubbard et al teach the administration of methylphenidate is widely used to treat children with ADD (page 944) and that in this study all children were administered 20 mg of MPH-SR (sustained release). The curve representing l-MPH from Patient profile 2 teaches an ascending sustained plasma concentration up to 6 hours. The claims contain the language "substantially ascending methylphenidate plasma drug concentration", while the specification technically only defines "ascending release rate". The specification (page 4, lines 6-13) discloses "It is believed to be particularly desirable to provide sustained release oral dosage forms that provide drug release at a substantially constant release rate over an extended time period. In this manner, for many drugs, the

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Section V. 35 U.S.C. 112 1st paragraph, written description

Correctness of 35 U.S.C 112 1st Paragraph, Written Description Rejections

Were all 35 U.S.C 112 1st paragraph, written description rejections reasonable? ○Yes ○ No

(No indicates potential clear error)

Comments:

Clarity of 35 U.S.C 112 1st Paragraph, Written Description Rejections

Were all 35 U.S.C 112 1st paragraph, written description rejections formulated in a clear manner? ○Yes ⊙ No

Comments:

35 U.S.C 112 1st Paragraph, Written Description Rejection(s) That Should Have Been Made

Give a brief description of the 112 1st paragraph, written description rejections that should have been

Claims 37, 49 and 50 (renumbered under Rule 126) are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
Vas-Cath Inc v. Mahurkar, 19 USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1117.
Applicant's invention is drawn to a method for treating ADD or ADHD in a patient, wherein the method comprises administering a pharmaceutically acceptable composition comprising 100 ng to 500 mg of methylphenidate and a pharmaceutically acceptable carrier to said patient in a manner that achieves a substantially ascending methylphenidate plasma drug concentration over a time period of about 5.5 hours following said administration. However, the claimed concentration of 100 ng to 500 mg is not disclosed within the instant specification. These claims were submitted by preliminary amendment but the declaration fails to refer to the submission of any preliminary amendment. The originally filed claims do not include the above noted concentration. Applicant might consider petitioning this issue and submitting a new declaration referring to the preliminary amendment in order to resolve the written description problem. In the meantime, the specific concentration of 100 ng to 500 mg of methylphenidate in claims 37, 49 and 50 is found to have no support in the instant specficiation.

ALLOWED REVIEW

Application Number	Notice Of Allowance	Examiner
09/802,709	05-Nov-03	FAY, ZOHREH A

Section XIII. Other Issues

Were all claims for priority properly treated?	◉ Yes	○ No	○ N/A
If a restriction was made, was it proper?	○ Yes	○ No	◉ N/A
Were all matters of substance in applicant's response and affidavits/declarations evaluated sufficiently?	○ Yes	◉ No	○ N/A
Other issues?	○ Yes	◉ No	

Applicant's argument regarding the Hubbard et al reference was not correctly evaluated by the examiner.

Comments:

If the rejection under 35 USC 102 is agreed upon, the Examiner should additionally set forth the following ODP rejection. Claims 37 and 46-50 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15, 88 and 90-95 of copending application no. 09/253,317. Although the conflicting claims are not identical, they are not patenably distinct from each other because they are both claiming a method for treating ADD or ADHD comprising administering methylphenidate at an ascending release rate. The dosage form comprises the same range of 100 ng to 500 mg and the time periods are equally covered. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The instant application 09/802,709 is a continuation of 09/253,317.

plasma drug concentration initially ascends for a short period of time as drug release begins and then remains substantially constant over an extended time period as drug release continues at a constant rate." Looking at the period of time for Patient Profile 2 between 6 and 12 hours the l-MPH is declining, but the level still remains consistently higher than the plasma level prior to the initial administration of MPH-SR. Although not included in this rejection, claims 49 and 50 could be considered as anticipated by Hubbard et al, in view of the case law to follow for interpreting "substantially". Hubbard et al teach "The plot of mean data (Figure 2) further supports this observation of sustained plasma concentration for both isomers up to 6 hours." (page 945) Hubbard concludes by stating "this pilot study demonstrated that despite higher plasma levels of d-MPH, the levels of both the enantiomers were sustained for over a period of 8 hours in all the six children with ADD or ADD-H dosed with 20 mg of MPH-SR." (page 947) In view of the inclusion of "sustained for over a period of 8 hours", further consideration should be given to claims 49 and 50 for this rejection.

A recent CAFC decision addresses the word "substantially" as not making a claim indefinite merely because it scope is not ascertainable from the face of the claims. (Amgen Inc. v. Hoechst Marion Roussel Inc., 65 USPQ2s 1385 (CAFC 2003), 1406) Thus, to properly understand and interpret "substantially" one should look to the specification for an understanding. In this case, page 4, lines 6-13 (as discussed above) of the instant specification provide the understanding that the drug is to be released at a substantially constant rate over an extended time period, thus providing an understanding for "substantially ascending methylphenidate plasma drug concentration over a time period".

The Examiner applied the Hubbard et al reference against claims 37 and 46-50 in paper #21 but referenced Patient Profile #3 which at best demonstrates an ascending release rate of 3-4 hours, if "substantially ascending" can be interpreted as still a higher plasma level than the initial administration level. The attorney argued that Profile #3 fails to support "ascending plasma drug formulation up to about 10 hours", which appears to be a correct assertion. Profile #3 does not meet the claim limitations, but Profile #2 does anticipate the instantly claimed invention for at least claims 37 and 46-48.

Origin of Prior Art used in the proposed 35 U.S.C. 102 rejection(s) above

☑ of record

☐ not of record (attach search logic/documentation)

☐ East ☐ EPO ☐ Other

☐ West ☐ JPO

☐ NPL ☐ Derwent

Comments: